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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/405,050 | 09/27/1999 | YEHUDA SHOENFELD | ZAP-1CIPCONC | 9070 |

7590 09/25/2003
JANE A MASSARO
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NEW YORK, NY 10020

EXAMINER

NAVARRO, ALBERT MARK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 09/25/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/405,050

Applicant(s)
Shoenfield et al

Examiner
Mark Navarro

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 22-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 23
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally Applicants amendment filed July 29, 2003 (Paper Number 22) has been received and entered. Consequently, claims 1-1 and 22-29 are pending in the instant application.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-2, 7-9 and 25-28 under 35 U.S.C. 102(b) as being anticipated by Chapel *et al* is withdrawn in view of Applicants amendment.
2. The rejection of claims 1-3, 7-11, 25 and 28 under 35 U.S.C. 102(b) as being anticipated by Morell *et al* is withdrawn in view of Applicants amendment.
3. The rejection of claims 1-3, 6-9, and 25-28 under 35 U.S.C. 102(b) as being anticipated by Besa *et al* is withdrawn in view of Applicants amendment.

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4. The rejection of claim 29 under 35 U.S.C. 102(b) as being anticipated by Vitetta *et al* is withdrawn in view of Applicants amendment.

Double Patenting

5. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,965,130 is maintained.

Applicant's have indicated a willingness to filed a terminal disclaimer to overcome this rejection, however until a terminal disclaimer is filed and made of record, this rejection is maintained for reasons of record in Paper Number 19.

6. The rejection of claims 1-11 and 22-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,562,902 is maintained.

Applicant's have indicated a willingness to filed a terminal disclaimer to overcome this rejection, however until a terminal disclaimer is filed and made of record, this rejection is maintained for reasons of record in Paper Number 19.

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Claim Rejections - 35 USC § 112

7. The rejection of claims 22-29 under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of “method for treating” is withdrawn.

The following new grounds of rejection are applied to the amended claims:

Claim Rejections - 35 USC § 112

8. Claims 1-11 and 22-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1-11 and 22-29 have been amended to recite “wherein the mammal has metastatic lymphoma.” Applicants point to support for this amendment at page 7, lines 4-6. “The intravenous immunoglobulins administered according to the present invention act as antimetastatic agents resulting in the reduction of tumor colony number as well as tumor colony size.”

However, this statement merely describes the mechanism of action of the administered IVIG, it does not provide support for only administering the IVIG to mammals which have metastatic lymphomas, while excluding those that may metastasize in the near future. In order to practice Applicants own claim language, one of skill in the art would be required to determine if a lymphoma diagnosed within an individual was at that precise moment in time undergoing

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metastasis. Only after determining that the lymphoma is currently metastasizing could one then proceed with administering the IVIG to inhibit the metastasis. Applicants specification is silent with regard to determining if the individual has currently ongoing metastasis prior to administering IVIG.

Applicant is required to demonstrate clear support for the phrase “wherein the mammal has metastatic lymphoma” (page and line number), or cancel the newly added material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

A handwritten signature in black ink, appearing to read 'Mark Navarro', with a stylized, wavy line extending from the end.

Mark Navarro

Primary Examiner

September 23, 2003